

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-768-200-1411

National Institute of Pharmacy and Nutrition
Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

medima

for the products / product categories:

Syringe infusion pumps
Volumetric infusion pumps
Docking stations for infusion pumps
IV infusion sets
Medical software

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-131-2007**

This certificate is valid until **2019-11-19** supposed that the results of the regular yearly surveillance audits are satisfactory.


Issued by EMKI as a Notified Body with identification number **1011**.



This certificate is valid only with the attachment.

Issue: 2

First issued: 2014-11-20

Budapest, 2016-10-13


Deputy General Director



Head of EMKI



EMKI 1551

The authenticity and validity of the certificate are verifiable at EMKI.

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
National Institute of Pharmacy and Nutrition
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1051 Budapest, Zrínyi u. 3. Fax: +36 1 886 94 60, Telefon: +36 1 225 27 39
H-1097 Budapest, Albert Flórián út 3/A, E-mail: cert@emki.hu, Web: www.emki.hu



ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate 5-768-200-1411

The certificate is valid for the following manufacturing site:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

The certificate is valid for the following models:

Syringe infusion pumps:
S, S1, S2, S-PCA, S100, S200, S300, S300 PCA

Volumetric infusion pumps:
P, P1, P2, P100, P200, P300

Docking stations for infusion pumps:
DS302, DS304, DS306, DS308

IV infusion sets:
Medima Line S
Medima Line B
Medima Line L

Medical software:
Medima User ToolBox
Medima Service ToolBox
MedimaNet

The detailed description of the products is kept by EMKI under No. 42-131-2007.

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